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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No. 10/764,231

Inventors: Gerald T. GOURDIN, et al.

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Docket No. PHEN234 CIP2

Customer No. 25235

Confirmation No.: 8493

Title: COMPOSITIONS
ENRICHED IN PHENOLIC
COMPOUNDS AND
METHODS FOR
PRODUCING THE SAME

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Declaration is submitted in support of patentably distinguishing features of product-by process claims pending in the above-referenced application.

1. I, Michael S. Tempesta, Ph.D., am a co-inventor of U.S. Patent Application No. 10/764,231.

2. My education is summarized as follows: I attended the University of Minnesota from 1974 to 1978, graduating with a B.A. in Chemistry. I then attended the University of Arizona from 1978 to 1981, graduating with a M.S. and a Ph.D. in Organic Chemistry. My Ph.D. Thesis was entitled *Structural Elucidation of Antitumor Agents from Plants*. I attended the Suntory Institute for Bioorganic Research in Japan from 1982 to 1983 as a Post doctoral Fellow. I attended Columbia University during 1983 as a Post-doctoral Fellow.

3. Appendix A attached hereto contain a partial list of publications which I have authored or on which I am a co-author or a co-inventor.

4. I have subsequently been employed as follows: From 1983 to 1990 I was an Assistant Professor of Organic Chemistry at the University of Missouri. I was employed by Shaman Pharmaceuticals, Inc. from 1990—1994, holding various positions, including, VP, Sr. VP and Chief Scientific Officer. I was employed by Larex, Inc. in the period 1995-1997 as Chief Scientific Officer. I held various positions at Pharmaprint, Inc. during the period 1997 to 1999, including Sr. VP, President, and R&D. I was President of Health Enhancement Products, Inc. during 2005. From 1996 to the present I have been an Independent General Partner of Technology Funding. In 1995 I founded and remain the President of Nat Prod Consulting Services.

5. I am presently a Managing Partner and co-owner of Phenolics, LLC, which is the assignee of all right, title and interest in and to U.S. Patent Application Serial No. 10/764,231.

6. On information and belief, U.S. Patent No. 5,200,186 ("the *Gabetta* patent"), which is a basis for rejection in the Office Action mailed November 2, 2005, in the above-referenced case, is owned by Indena S.P.A. The title page of the *Gabetta* patent, Invernì Della Beffa S.P.A. is listed as the assignee. According to U.S. Patent & Trademark Office on-line "Assignments on the Web", Invernì Della Beffa S.P.A. recorded a name change to I D B Holding S.P.A. as executed March 21, 1995, and then as executed March 27, 1995, I D B Holding S.P.A. then assigned its interest in the *Gabetta* patent to Indena S.P.A. ("*Indena*").

7. *Indena* currently markets a bilberry extract under "Mirtoselect®, The Original Bilberry Extract (From *Vaccinium myrtillus* L.). On information and belief, this product is manufactured generally in accordance with one or more of the Examples of the *Gabetta* patent, first involving addition of sodium bisulfite and then requiring removal of sulfur dioxide.

8. I recently contacted *Indena* and requested a sample of their commercial bilberry extract. On information and belief, the sample was shipped to

me directly from *Indena*. I submitted the sample to Desert Analytics of Tucson, Arizona, which subsequently reported on a Certificate of Analysis a total sulfur content of 560 ppm.

9. In my opinion, the presence of 560 ppm sulfur in the *Indena* bilberry extract sample (a) is indicative of the incomplete removal of the sulfur added during the bilberry extraction process as sodium bisulfite, and (b) is evidence that the composition produced with the *Gabetta* extraction process is different than that produced according to the method claimed in the present invention, in which sodium bisulfite or other forms of sulfur are not added or required.

10. On information and belief, it has been estimated that one in 100 people are sulfite sensitive to some degree, but for the 10% of the population who are asthmatic, up to 5% are at risk of having an adverse reaction to the substance. Significant sulfite sensitivity reactions occur in susceptible asthmatics. A subgroup of serious concern is the sulfite-sensitive asthmatic population. Of those, severe reactions have been reported in persons where are steroid-dependent and are taking such drugs as prednisone or methylprednisolone. Most of these individuals have been cautioned by their doctor to avoid sulfite-containing foods or beverages. The number of asthmatic patients that are included in this sulfite sensitive group is estimated to be 500,000 in the United States.

11. On information and belief, the symptoms of a sulfite sensitivity reaction vary from mild to life-threatening. Common symptoms are mild and involve a skin rash accompanied by redness, hives, itching, flushing, tingling, and swelling. Respiratory symptoms include difficulty breathing, wheezing, and stridor. Gastrointestinal reactions involve nausea and stomach cramps. Much less common but more serious signs and symptoms of sulfite sensitivity are low blood pressure, shock, extreme difficulty breathing and loss of consciousness. As noted above, these symptoms of a severe reaction are most apt to occur in the steroid-dependent asthmatic person.

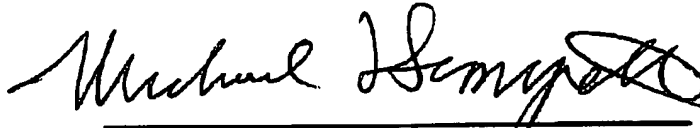
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and

further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the U.S. Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

Date:

3-31-06



Michael S. Tempesta, Ph.D.



APPENDIX A

Cytotoxic Agent from *Penstemon deustus* (Scrophulariaceae): Isolation and Stereochemistry of Liriodendrin, A Symmetrically Substituted Furofuranoid Lignan Diglucoside. Shivanand D. Jolad, Joseph J. Hoffmann, Jack R. Cole, Michael S. Tempesta and Robert B. Bates. *J. Org. Chem.* **1980**, *45*, 1327-1329.

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